

PSJ3

Exhibit 467



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

September xx, 2011

William T. Winsley, M.S., R.Ph.
Executive Director
Ohio Board of Pharmacy
77 S. High Street, Room 1702
Columbus, Ohio 43215-6126

RE: Proposed Rules -- O.A.C. 4729-5-20 (Prospective Drug Utilization Review)

Dear Mr. Winsley:

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

On behalf of its members operating approximately 1,674 retail pharmacies in the state of Ohio, the National Association of Chain Drug Stores (NACDS) thanks the Ohio State Board of Pharmacy ("Board") for considering our comments on proposed rule revisions to O.A.C. 4729-5-20 pertaining to when pharmacists must check the Ohio Automated Rx Reporting System (OARRS). Prescription monitoring programs like OARRS can be useful tools for prescribers and dispensers to identify potential prescription drug misuse and abuse. Thus, we welcome the opportunity to work with the Board to ensure that this tool is used in the most efficient and effective manner by dispensers. We appreciate the opportunity to present our perspectives to the Board on this subject.

➤ ***Targeted Approach to Use of OARRS Data.*** Under the proposed rule, the Board has added language to establish criteria which, if met, would require pharmacists to check the OARRS database prior to dispensing a prescription to patients. Under these criteria, dispensing pharmacists would be required to review information that would have otherwise been reviewed by a prescriber at the point when the prescriber issued a particular prescription. This redundancy could be *ideally* eliminated by revising the rule to simply require that pharmacists check the OARRS database in the following circumstances:

- If a pharmacist becomes aware of a person abusing or misusing reported drugs (i.e. over-utilization, early refills, or appears overly sedated or intoxicated upon presenting a prescription for a reported drug);
- If a pharmacist becomes aware of the person requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area)

If the Board determines that this is not an acceptable approach, there are additional ways that the Board could focus the proposed rule language to target the circumstances that are likely indicators of prescription drug misuse and abuse. One approach would be to require pharmacists to check the OARRS database for the top abused reportable drugs in

(703) 549-3001
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www.nacds.org

the state of Ohio. This would enable pharmacists to focus their efforts on identifying patients potentially misusing and abusing reportable drugs based on the diversion trends in the state of Ohio. Further, such a list of drugs could be expanded out if necessary in the future as appropriate. Notably, this approach would not prevent pharmacists from checking the OARRS database when patients present a prescription for another reportable drug and pharmacists feel it would be appropriate to check the dispensing history.

Alternatively, the Board should consider focusing the current criteria in the rule as follows:

- Only require pharmacies to check the OARRS database when the prescription is paid for in cash. Prescriptions paid for by third party payors, including Medicaid, are not likely to dispensed in excessive amounts, as the payors are very watchful of the number and types of drugs that they will pay for. If a patient exceeds an acceptable threshold, the payor will deny the claim. At that point, the patient would then become a cash paying patient, and the pharmacists would then be required to check OARRS.
- The proposed rule would require pharmacists to check the OARRS database when a patient is obtaining controlled substances from “multiple prescribers.” “Multiple” can mean as few as two, and many patients would fall into this category just based on how our healthcare system works. For example, a patient who had undergone a surgery and was released from the hospital might get their first prescription from the surgeon, and then another from their rehabilitation doctor, and yet another when their care is finally transferred to their regular physician. Likewise, patients with chronic illnesses that are treated in a practice where they see multiple physicians based on whoever is in the office during a particular week could obtain prescriptions from any of the doctors at that practice. Arguably, most patients obtaining controlled substances prescriptions are not misusing controlled substances, and requiring pharmacists to check based on this criteria would be unnecessarily burdensome. The Board should instead consider specifying an exact number rather than use the term “multiple prescribers.” One option might be to use the same criteria specified in the NASPER grant guidelines that triggers unsolicited reporting to prescribers / dispensers. Specifically, if a patient is obtaining controlled substances prescriptions six or more different prescribers, then that would trigger the check.
- The proposed rule would require pharmacists to check the OARRS database if the person requests a drug by a specific color or street name. This is problematic. Many patients don’t know the specific name of medication, and they come into a pharmacy and ask for their “yellow pill”. That alone should not trigger a report, especially if it is a refilled or renewed prescription. Also, most pharmacists do not know the street names of drugs; thus, it would be inappropriate to require pharmacists to check the OARRS database when patients make references that they don’t understand.
- Eliminate the requirement for pharmacists to check OARRS when a person is receiving a reported drug for more than 12 weeks. Many patients with chronic illnesses legitimately receive controlled substances prescriptions for up to a six month

supply. For example, an eight year old on ADD medication might fall into this category. In such an instance, this criteria would not be reasonable.

Miscellaneous Items. Beyond the issues raised above, there are certain items in the proposed rule that we would ask the Board to further clarify. First, the proposed language establishing the criteria under which pharmacists would be required to check the OARRS database is notably being added into the section of the rule that addresses the requirements for drug utilization review for *all* prescription medications. The proposed new language outlining the requirement specifies that pharmacists must check the OARRS database prior to dispensing a “prescription.” This language could be read to mean *any* prescription drug, not just those that are reportable to OARRS. While that is likely not the intent of the Board, the proposed rule language should be modified to clarify that pharmacists would only need to check the OARRS database prior to dispensing a drug that is reportable to OARRS (or the most abused / diverted reportable drugs, depending on how the Board otherwise revises the scope of the rule.)

Additionally, the proposed rule criteria would require pharmacists to check OARRS if the pharmacist becomes aware that the person “requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area) or when the person “presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population. The term “geographic care area” is vague. We request that the Board further clarify what is meant by the term “geographic care area” if the Board opts to adopt this criteria.

Finally, we would ask the Board to establish a process to allow pharmacy technicians to log onto OARRS as the pharmacist’s agent and pull specific patients data for pharmacists to review. One of the key challenges for accessing information in the OARRS database is the time that it takes to log on and look up patient data. Allowing pharmacy technicians to perform this activity will make the process more efficient and allow pharmacists to better utilize their time on the many other activities that require their professional judgment..

NACDS thanks the Board for considering our comments. Please do not hesitate to contact me with any questions or for further assistance. I can be reached at: (703) 837-4289 or JMCCORMACK@NACDS.ORG.

Sincerely,